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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/621,684	07/17/2003	Scott A. Waldman	TJU-2858	1770

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WOODCOCK WASHBURN LLP  
ONE LIBERTY PLACE, 46TH FLOOR  
1650 MARKET STREET  
PHILADELPHIA, PA 19103

EXAMINER

PONNALURI, PADMASHRI

ART UNIT PAPER NUMBER

1639

DATE MAILED: 10/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b> <i>Restriction purposes only</i>	<b>Application No.</b> 10/621,684	<b>Applicant(s)</b> WALDMAN, SCOTT A.	
	<b>Examiner</b> Padmashri Ponnaluri	<b>Art Unit</b> 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-10, drawn to a conjugated compound comprising a ST receptor binding moiety, and an active agent<sup>a radio stable agent</sup>; and a pharmaceutical composition comprising the conjugate, classified in class 514, subclass 2.
  - II. Claim 11, drawn to a method of treating an individual suspected of suffering from metastasized colorectal cancer, classified in class 436, subclass 64.
  - III. Claims 12-19, drawn to a pharmaceutical composition comprising a pharmaceutically acceptable carrier; a conjugate comprising a ST receptor binding moiety, and a radioactive agent, classified in class 424, subclass 1.11.
  - IV. Claim 20, drawn to a method of radio imaging metastasized colorectal cancer cells, classified in class 436, subclass 504.
  - V. Claim 21, drawn to a method of treating an individual suspected of suffering from metastasized colorectal cancer by administering a pharmaceutically active carrier, a conjugate comprising a ST receptor binding moiety; and radio stable agent, classified in class 436, subclass 57.
  - VI. Claim 21, drawn to a method of treating an individual suspected of suffering from metastasized colorectal cancer by administering a pharmaceutically active carrier, a conjugate comprising a ST receptor binding moiety; and radio active agent, classified in class 436, subclass 57.

- VII. Claim 22, drawn to a method of delivering a nucleic acid to intestinal tracer cells a pharmaceutical composition comprising a) a pharmaceutical carrier; b) a composition comprising a ST receptor ligand, and a nucleic acid molecule, classified in class 435, subclass 6.

### ***Further Restriction***

In addition Group I detailed above reads on patentably distinct Groups. Group I is further divided into multiple groups each representing a different conjugate. The different ST receptor binding moiety (i.e., SEQ ID NO 2, 3, 5-56, fragments, and derivatives) do not have a distinguishable core structure. And further the radio stable active moiety in the conjugate is structurally and functionally different (i.e., bacterial toxins, enzymes, antibiotics), and belong to different class of compounds, and unrelated to each other, which in turn with the combination of the ST receptor binding moiety would result in several different conjugates. Thus a further restriction is applied to group I.

**The elected further Group must result in a single specific conjugate, i.e., a conjugate comprising a) SEQ ID NO: 2, as ST receptor binding moiety; and b) methotrexate as the active moiety.**

**This requirement is not to be taken as an election of species, but rather as an election of a single invention, since each product is assumed to be a patentably distinct invention, in the absence of evidence to the contrary.**

The inventions are distinct, each from the other because of the following reasons:

2. Inventions of group I and group III are drawn to different conjugate compositions. Group I conjugate compositions have a ST receptor binding moiety, a radio stable agent; which is

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different from the group II conjugate compositions comprising a ST receptor binding moiety, and a radioactive agent. The compositions of group I and group III are not disclosed as capable of use together and they have different reagents, different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Thus, restriction between the groups is proper.

3. Inventions of groups II, IV, V, VI, VII are all drawn to different methods. The different methods use different reagents, and the result of the each method is different. The inventions of groups II, IV, V and VI are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

4. Inventions of group I (products) and group II (method) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the group I multiple products (see the further restriction) can be used in the group II method. Thus, restriction between the groups is proper.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. Even though the groups are classified in the same class/subclass, this has no effect on the non-patent literature search. Different inventions or groups would require completely different searches in non-patent databases, and there is no exception that the searches would be co-

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extensive. Therefore, these do not create an undue search burden, and restriction for examination purposes as indicated is proper.

7. This application contains claims directed to the following patentably distinct species of the claimed invention:

8. If applicants elect either group II, III, IV, V or VI, applicants are further requested to elect a single species for each of the following:

- a) A single species of ST receptor binding moiety;
- b) A single species of radio active agent;
- c) A single species of radio stable agent (groups II, V);
- d) A single species of ST receptor ligand (group VII).

The different species of each of groups (a-d) are structurally and functionally different from each other and do not require the other for ultimate use. Thus the species election is proper.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

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the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

9. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmashri Ponnaluri whose telephone number is 571-272-0809. The examiner is on Increased Flex Schedule and can normally be reached on Monday through Friday between 7 AM and 3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Padmashri Ponnaluri  
Primary Examiner  
Art Unit 1639

30 September 2004

  
PADMASHRI PONNALURI  
PRIMARY EXAMINER